



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0737; FRL-10688-01-OCSP]

Diglycerol in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule and correction.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of diglycerol when used as an inert ingredient (plasticizer) on growing crops and raw agricultural commodities pre- and post-harvest. This regulation eliminates the need to establish a maximum permissible level for residues of diglycerol, when used in accordance with the terms of the exemption. This regulation also amends the tolerance exemption 2,6-pyridinedicarboxylic acid by correcting the CAS Reg. No.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0737, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-2875; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0737 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing

Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0737, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Petition for Exemption

In the *Federal Register* of September 23, 2022 (87 FR 58047) (FRL-9410-05-OSCPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11673) by RRStewart Consulting, LLC, on behalf of Aicello America Corporation, 182 Nassau Street, Princeton, NJ 08542. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of diglycerol (CAS Reg. No. 59113-36-9) when used as an inert ingredient (plasticizer)

in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest. That document referenced a summary of the petition prepared by RRStewart Consulting, LLC, on behalf of Aicello America Corporation, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

On November 23, 2022, (87 FR 71523) (FRL-10400-01-OCSPP), the exemption from the requirement of a tolerance was published for 2,6-pyridinedicarboxylic acid; however, the rule inadvertently included an error in the CAS Reg. No. This document also corrects (CAS Reg. No. 449-83-2) to read (CAS Reg. No. 499-83-2) under 40 CFR 180.910.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in

residential settings but does not include occupational exposure. When making a safety determination for an exemption for the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs EPA to take into account the considerations in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) lists other factors for EPA's consideration in making safety determinations, *e.g.*, the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among other factors.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diglycerol, including exposure resulting from

the exemption established by this action. EPA's assessment of exposures and risks associated with diglycerol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by diglycerol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicological database of diglycerol is supported by data regarding glycerol and polyglycerol. EPA has determined that it is appropriate to bridge glycerol and polyglycerol data to assess diglycerol due to similarities in functional groups/structure.

Diglycerol exhibits low levels of acute toxicity via the oral and dermal routes of exposure, and it is anticipated to have low acute inhalation toxicity. Diglycerol is not an acute skin or eye irritant nor a skin sensitizer.

Portal-of-entry effects (squamous metaplasia of the epithelium lining the base of the epiglottis) were observed in the available subchronic inhalation toxicity study. There is no evidence of offspring susceptibility in the available developmental toxicity study or in the 2-generation reproductive toxicity study with the surrogate chemical glycerol. No effects on reproductive parameters were observed in the 2-generation reproductive toxicity study with glycerol. Concern for carcinogenicity is low, based on negative results in mutagenicity and genotoxicity studies and lack of treatment-related neoplastic effects in the available chronic toxicity study in rats. No evidence of neurotoxicity or immunotoxicity was seen in the available studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The hazard profile of diglycerol is adequately defined. No acute dietary, chronic dietary, incidental oral, or dermal endpoints were selected because no adverse effects were identified following dietary exposure to diglycerol or related compounds. The short-term inhalation endpoints are selected from the inhalation toxicity study in rats, with a no observed adverse effect concentration (NOAEC) of 0.165 mg/L and a lowest observed adverse effect concentration (LOAEC) of 0.66 mg/L, based on squamous metaplasia of the epithelium lining the base of the epiglottis.

C. Exposure Assessment

1. *Dietary exposure.* Dietary exposure (food and drinking water) may occur from consuming food treated with pesticide formulations containing this inert ingredient and from non-pesticidal uses (*e.g.*, personal care products). However, no dietary endpoints of concern

were identified, and therefore, a quantitative dietary exposure assessment for diglycerol was not conducted.

Based on the lack of treatment-related tumors in the carcinogenicity study in rats and the lack of mutagenicity in the available *in vitro* studies, diglycerol is considered not likely to be carcinogenic. Therefore, a cancer dietary exposure assessment was not performed.

2. *Residential exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, etc.). Diglycerol may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. For residential handlers, the Agency assumed handlers may receive short-term dermal and inhalation exposure to diglycerol from formulations containing the inert ingredient in outdoor and indoor scenarios. However, as dermal endpoints were not selected, margins of exposure (MOEs) were only calculated for inhalation exposure scenarios. For residential handler short-term outdoor and indoor exposure scenarios, inhalation MOEs ranged from 23,000 to 940,000 and are not of concern (*i.e.*, the level of concern (LOC) for inhalation exposure is for MOEs that are less than 100). Residential handler intermediate-term and long-term exposures are not calculated because applications are not expected to occur daily or for more than 30 days.

Residential post-application scenarios include short- and intermediate-term dermal (skin contact with treated surfaces) exposure for adults and children as well as short- and intermediate-term incidental oral exposure for children (hand-to-mouth exposure with treated surfaces). However, no dermal or dietary endpoints were selected for diglycerol and therefore, a post-application exposure assessment was not performed.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism

of toxicity.”

Unlike pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to diglycerol and any other substances, and diglycerol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that diglycerol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the evaluation of available toxicity studies, there is low concern for pre- and postnatal susceptibility for infants and children from exposure to diglycerol. The FQPA safety factor has been reduced to 1X because: (1) the toxicity database is adequate to characterize potential pre- and postnatal risk for infants and children; (2) no developmental or reproductive effects were observed in the available reproduction toxicity and developmental studies; (3) no evidence of neurotoxicity was observed in the database; and (4) the assumptions for the exposure assessment are unlikely to underestimate risk.

E. Aggregate Risks and Determination of Safety

In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (*e.g.*, a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure.

1. *Acute aggregate risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. However, there was no hazard attributable to a single exposure seen in the toxicity database for diglycerol. Therefore, diglycerol is not expected to pose an acute aggregate risk.

2. *Short-term aggregate risk.* Short-term aggregate exposure takes into account short-term residential (dermal and inhalation) exposure plus chronic dietary exposure (food and drinking water). However, there was no hazard attributable to chronic dietary or dermal exposure. Therefore, the short-term aggregate risk is equal to the inhalation exposure risk, which is not of concern.

3. *Chronic aggregate risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. However, there was no hazard attributable to chronic dietary exposure. Therefore, diglycerol is not expected to pose a chronic aggregate risk.

4. *Cancer aggregate risk.* EPA has not identified any concerns for carcinogenicity relating to diglycerol. Therefore, diglycerol is not expected to pose a cancer aggregate risk.

5. *Determination of safety.* Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to diglycerol residues. More detailed information on this action can be found in the “Diglycerol. Human Health Risk Assessment and Ecological Effects Assessment to Support Inert Ingredient Approval for use in Pesticide Formulations” in docket ID EPA-HQ-OPP-2022-0737.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of diglycerol (CAS Reg. No. 59113-36-9) when used as an inert ingredient (plasticizer) in pesticide formulations applied to growing crops and raw agricultural commodities pre- and post-harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*),

do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 2023.

Daniel Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, amend table 1 to 180.910 by:

a. Adding in alphabetical order an entry for “diglycerol” and

b. Revising the entry for “2,6-Pyridinedicarboxylic acid”.

The addition and revision read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

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Table 1 to 180.910

Inert ingredients	Limits	Uses
* *	*	* * *
Diglycerol (CAS Reg. No. 59113-36-9)		Plasticizer
* * * * *		
2,6-Pyridinedicarboxylic acid (CAS Reg. No. 499-83-2)	Not to exceed 2 ppm	Stabilizer
* *	*	* * *